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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,816	05/15/2001	Hirota Uchiyama	8083	9687

27752 7590 08/13/2003

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EXAMINER
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HARDEE, JOHN R

ART UNIT	PAPER NUMBER
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1751

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/855,816

Applicant(s)

UCHIYAMA ET AL.

Examiner

John R Hardee

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-- The MAILING DATE of this communication appears on the c ver sh et with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,9,14,18,23,26,29,34,42,43 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2-8,10-13,15-17,19-22,24,25,27,28,30-33,35-41,44-51 and 53-59.

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**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Example IV in Paper No. 5 is acknowledged.

The traversal is on the ground(s) that the elected example reads on claim 1, and

applicant should therefore be entitled to prosecute all of the claims which depend from

this claim. This is not found persuasive because the elected species MUST read on the

~~independent claim in order for the election to be responsive. Furthermore if applicant~~

~~were invariably entitled to examination of each and every embodiment that his~~

~~independent claim reads on, there would be no point in requiring a species election.~~

Applicant is entitled to search and examination of his elected example, and further

search and examination until non-elected subject matter is found, up to a reasonable

number of species.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's choice of claims is puzzling; how can claim 14 read on the Example,

but not claim 13, from which it depends? Or claim 26, but not claims 24 and 25? Or 29,

but not 27 and 28? Or 55-59, and not 52? Why does claim 12 read on the invention if

the composition contains 1% of cyclodextrin? It is not clear what the utility of the

exemplified compositions is. Accordingly, it cannot be determined which method claims

read on these compositions. As a courtesy to applicant, the examiner has considered

method claim 52.

3. Claims 2-8, 10-13, 15-17, 19-22, 24, 25, 27, 28, 30-33, 35-41, 44-51 and 53-59

are withdrawn from consideration by the examiner as being drawn to embodiments non-

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elected with traverse, the election having been timely traversed in Paper No. 5. Claim 12 is withdrawn from consideration by the examiner as it clearly does not read on the elected example.

### ***Claim Objections***

4. Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This claim restates the limitations of claim 18.

### ***Double Patenting***

5. Claim 52 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,436,442 B1. This is a double patenting rejection. While the other process claims are withdrawn from consideration, the examiner suggests that they be reviewed carefully for other duplicate claims.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 9, 14, 18, 42 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,436,442 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite processes for making the compositions of the present claims and, in fact, the composition of claim 1 is claimed in patented claim 17. Accordingly, it would have been obvious at the time the invention was made to make the compositions presently claimed, because the patented claims recite methods for making same.

#### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 14, 23, 26 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claim 23, what compatible hydrotrope is present in Example IV? How is one to know what its complexation constant is? Regarding claim 14, how can one determine from the specification what surfactant has a complexation constant

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greater than 8000/M? Regarding claims 26 and 29, how can one tell from the specification what surfactants and combinations of surfactants have the recited CMC values?

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 9, 14, 18, 26, 29, 34, 42, 43 and 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ogino et al., US 4,678,598. See Inventive Compositions 1-5 and 6-11. Regarding CMC and complexation values, these compositions contain surfactants which applicant's specification indicates are compatible or non-compatible with cyclodextrins, and would appear to meet, to the extent this can be determined from the specification, the recited CMC and complexation values.

***Allowable Subject Matter***

12. All of the examples appear to be allowable over the prior art of record. Claims reciting all of the ingredients of these compositions, commensurate in scope with the amounts of those ingredients, would be allowable. The closest prior art of record is the

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reference relied upon above, which does not disclose or motivate the formulation of a composition comprising all of the disclosed ingredients in any of the examples.

Any prior art made of record and not relied upon is of interest and is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to the examiner, Dr. John R. Hardee, whose telephone number is (703) 305-5599. The examiner can normally be reached on Monday through

Friday from 8:00 until 4:30. In the event that the examiner is not available, his supervisor, Dr. Yogendra Gupta, may be reached at (703) 308-4708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'J. Hardee', with a stylized, cursive script.

John R. Hardee  
Primary Examiner  
August 5, 2003